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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALEXANDER D. SLOWEY,
SUSANNAH C. BOSWELL, and PHILLIP A. JINKS

Appeal 2009-002795[1]
Application 10/509,184
Technology Center 1600

Decided: August 31, 2009

Before DEMETRA J. MILLS, LORA M. GREEN, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an aerosol vial containing a pair of asthma-treating drugs combined with a propellant and a bulking agent. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

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[1] 3M Company is the real party in interest (App. Br. 3).

STATEMENT OF THE CASE

Appellants have found that the use of a particulate bulking agent having a mass median diameter of less than one micron in *aerosol compositions* comprising formoterol and mometasone dispersed in HFC 134a, HFC 227 or mixtures thereof, allows the provision of dispersions of both drugs showing desirably high physical stability and homogeneity. (Spec. 3.)

Claims 1-14 and 17 are pending and on appeal (App. Br. 2-3). Claim 1 is representative and reads as follows:

> 1. A dispenser comprising an aerosol vial equipped with a dispensing valve, said aerosol vial containing a pharmaceutical aerosol formulation comprising particles of (a) formoterol or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof and (b) mometasone or a pharmaceutically acceptable salt, solvate, or physiologically functional derivative thereof dispersed in a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof, and a bulking agent having a mass median diameter of less than one micron, and wherein an interior surface of the aerosol vial is coated with a fluorocarbon polymer.

The Examiner cites the following documents as evidence of unpatentability:

Ashurst	US 6,131,566	Oct. 17, 2000
Trofast	WO 00/53187 A1	Sep. 14, 2000

Claims 1-14 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Trofast and Ashurst (Ans. 3-6).

OBVIOUSNESS

ISSUE

The Examiner cites Trofast as teaching a composition having all of the claimed ingredients, but concedes that the reference "do[es] not teach coating the interior surface of the aerosol vial with a fluorocarbon polymer. It is for this that Ashurst et al. is joined" (Ans. 5).

The Examiner cites Ashurst as teaching that "some aerosol drugs tend to adhere to the inner surfaces of inhalers and that coating the interior surfaces can reduce the problem of adhesion or deposition on the can walls" (*id.*). Based on the two references' teachings, the Examiner concludes that an ordinary artisan would have considered it obvious "to make an aerosol composition comprising particles of formoterol, a propellant and a bulking agent, contained in a dispenser comprising an aerosol vial that is coated with a fluorocarbon polymer" (*id.* at 5-6).

The Examiner finds that, "although the coated interior surfaces of Ashurst et al. is used for albuterol, the same holds true for drugs that adhere to the interior walls of aerosol vials" (*id.* at 6). Thus, the Examiner reasons, "[b]ecause formoterol adheres to the interior wall of aerosol vials, it is reasonable for one of ordinary skill to look to the combined teaching of Trofast et al. and Ashurst et al. for a solution to the problem of undesired adhesion" (*id.*).

Appellants contend, among other things, that the Examiner erred in finding that Trofast suggests a composition with a bulking agent in combination with the other ingredients recited in claim 1 (App. Br. 5). Specifically, Appellants argue, Trofast distinguishes between the ingredients suitable for use in pressurized metered dose inhalers (MDIs), which use

propellants, and dry powder inhalers (DPIs), which do not use propellants (*id.*).

Thus, Appellants urge, when taken in light of other disclosures in the reference, Trofast's teaching that its formulations can contain a "diluent or carrier" that corresponds to the claimed bulking agent "appears to be directed to the context of a DPI formulation and not as an MDI bulking agent" (*id.*). Accordingly, Appellants contend, "the Examiner has not established a *prima facie* case of obviousness" (*id.* at 6).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether Appellants have demonstrated that the Examiner erred in finding that Trofast teaches or suggests a composition that includes a bulking agent in combination with formoterol, mometasone, and the claimed propellants.

FINDINGS OF FACT ("FF")

1. Trofast discloses using "the steroidal anti-inflammatory drug mometasone (preferably in the form of its furoate ester) in combination with the long-acting bronchodilator formoterol (preferably as the fumarate dihydrate salt) for the treatment of respiratory disorders such as mild, moderate and severe asthma, rhinitis and COPD" (Trofast 1).

Trofast discloses that "a first aspect the invention therefore provides a pharmaceutical combination comprising:

(a) formoterol, a pharmaceutically acceptable salt or solvate thereof;

(b) mometasone or an ester thereof and optionally a solvate (e.g. mono-hydrate) thereof;

and optionally

(c) one or more pharmaceutically acceptable additives, diluents or carriers[.]"

(*Id.* at 3.)

2. Trofast discloses:

> The combination can be inhaled from a nebulizer, from a pressurized metered dose inhaler or as a dry powder from a dry powder inhaler e.g. multidose reservoir systems from Astra (Turbuhaler®) or Schering-Plough or from a dry powder inhaler utilizing gelatine, plastic or other capsules, cartridges or blister packs. A diluent or carrier, generally being non-toxic and chemically inert to the medicament e.g. lactose, dextran, mannitol or glucose or any additives that will give the medicament a certain taste can be added to the powdered medicament in an amount of from 50 μg to 25 mg per dose, more preferably in an amount of from 50μg to 10 mg, most preferably in an amount of from 100 to 2000 μg. One or more of the ingredients is preferably in the form of a dry powder, more preferably a micronized dry powder, most preferably an agglomerated micronized dry powder. As an alternative to agglomeration, the finely divided active ingredients may be in the form of an ordered mixture with the pharmaceutically acceptable additive, diluent or carrier. An ordered mixture comprises fine particles of an active ingredient in association with coarse particles of the pharmaceutically acceptible [sic] additive, diluent or carrier. A fraction of fine particles of carrier may also be present. The ingredients used in the invention can be obtained in these preferred forms using methods known to those skilled in the art. The particle size of the active ingredients is less than 20 μm, preferably less than 10 μm.

(*Id.* at 5-6.)

3. The following paragraph in Trofast reads as follows:

> When the ingredients of the system are adapted to be administered from a pressurized inhaler (pMDI), they are preferably in micronized form. They are dissolved, or,

> preferably suspended in a liquid propellant mixture. The propellants which can be used include chlorofluorocarbons, hydrocarbons or hydrofluoroalkanes. Especially preferred propellants are P134a (tetrafluoro-ethane) and P227 (heptafluoropropane) each of which may be used alone or in combination. They are optionally used in combination with one or more other propellants and/or one or more surfactants and/or one or more other excipients, for example ethanol, a lubricant, an anti-oxidant and/or a stabilising agent.

(*Id.* at 6.)

4. Trofast's examples consist of eight different compositions (*id.* at 7-8). The compositions in Examples 1 through 3 contain only formoterol and mometasone (*id.* at 7).

5. The compositions in Examples 4-6 contain formoterol, mometasone, and lactose monohydrate (*id.* at 7-8).

6. The compositions in Examples 7 and 8 contain formoterol, mometasone, propellant(s), ethanol and oleic acid (*id.* at 8).

7. An "aerosol" is defined as, "a substance, such as a drug containing therapeutically active ingredients, packaged under pressure with a gaseous propellant for release as a spray of fine particles." The *American Heritage Medical Dictionary* on line, http://www.yourdictionary.com/medical/aerosol

PRINCIPLES OF LAW

> In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. "[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references."

In re Fritch, 972 F.2d 1260, 1265 (Fed. Cir. 1992) (citations omitted, bracketed material in original).

In *KSR Int' l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question. The Court nonetheless reaffirmed that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 418.

Rather, as the Court stated:

> [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does* . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 418-419 (emphasis added); *see also id.* at 418 (requiring a determination of "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue") (emphasis added).

Ultimately, therefore, as our reviewing court has stated, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

Moreover, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

When evaluating claims for obviousness, "the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill." *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986). Thus, "'[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.'" *Id.* (quoting *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965)).

ANALYSIS

We agree with Appellants that the Examiner erred in finding that Trofast teaches or suggests a composition that includes a bulking agent in combination with formoterol, mometasone, and the claimed propellants.

We acknowledge Trofast's disclosure that lactose, dextran, mannitol, or glucose, can be included in its compositions (FF 2). Appellants do not dispute that those ingredients are encompassed by the term "bulking agent" in claim 1.

Appellants' claim 1 is directed to a dispenser comprising an aerosol vial containing an aerosol composition. However, the relevant teaching in Trofast states that "[a] diluent or carrier, generally being non-toxic and chemically inert to the medicament e.g. lactose, dextran, mannitol or glucose or any additives that will give the medicament a certain taste *can be added to the powdered medicament*" (FF 2 (emphasis added)). This sentence immediately follows a sentence stating that "[t]he combination can be inhaled from a nebulizer, from a pressurized metered dose inhaler or as a dry

powder from a dry powder inhaler e.g. multidose reservoir systems from Astra (Turbuhaler®) or Schering-Plough or from a dry powder inhaler utilizing gelatine, plastic or other capsules, cartridges or blister packs" (*id.*).

Thus, Trofast states that the bulking agent can be added to the powdered medicament, and that statement immediately follows a teaching that distinguishes between dry powder inhalers, nebulizers, and pressurized metered dose inhalers. Given these facts, we agree with Appellants that an ordinary artisan reading Trofast's disclosures in context would understand Trofast as teaching that the bulking agents were to be added to the inhaled dry powdered compositions, and not the nebulizers or metered dose inhalers.

This interpretation of the reference is buttressed by the fact that Trofast discusses metered dose inhalers in the following paragraph without mentioning the previously discussed diluent, carrier, lactose, dextran, mannitol, glucose, or taste-enhancing additives (*see* FF 3). Rather, Trofast discloses using the propellants encompassed by claim 1, "in combination with one or more other propellants and/or one or more surfactants and/or one or more other excipients, for example ethanol, a lubricant, an anti-oxidant and/or a stabilising agent" (*id.*). Thus, in addition to *not* mentioning the diluents and carriers previously described as being useful in dry powdered inhalers, Trofast teaches that metered dose inhalers containing the propellants recited in claim 1 use different types of excipients, i.e., ethanol, a lubricant, an antioxidant and/or a stabilizing agent.

Appellants' interpretation of Trofast is further supported by the fact that none of the exemplified compositions that contain lactose also contain propellants (*see* FF 5). Conversely, while the exemplified compositions that contain propellants also contain ethanol and oleic acid, none of the

propellant-containing compositions contains an additive that the Examiner alleges as being a bulking agent, much less a bulking agent having the claimed particle size (*see* FF 6).

Thus, we agree with Appellants that when the relevant teachings of Trofast are read as whole, and in context, an ordinary artisan would not interpret them as teaching or suggesting the use of a bulking agent as claimed in a propellant-containing composition. Moreover, the Examiner does not point to, nor do we see, any disclosure in Ashurst that remedies this deficiency in Trofast.

The Examiner argues that, at page 6, lines 13-20, Trofast teaches that "the ingredients can be adapted to be administered via a pressurized inhaler. It is the position of the examiner that the 'ingredients', as taught, includes the composition as disclosed on page 3, lines 14-18, which includes one or more pharmaceutically acceptable additives, diluents or carriers" (Ans. 6).

We are not persuaded by this argument. While it is true that Trofast provides a generic statement of ingredients suitable for its compositions (FF 1), that disclosure must be viewed in light of other teachings in the reference.

As discussed above, Trofast distinguishes between the additives it considers useful for compositions inhaled as dry powders, and the additives suitable for propellant-containing compositions inhaled via metered dose inhalers. Given the reference's distinction between the ingredients suitable for the two types of compositions, we agree with Appellants that, despite the more generic disclosure on page 3 of Trofast, the reference's more specific disclosure would not have prompted an ordinary artisan to include the

additives described as being suitable for powdered inhalers in propellant-containing compositions.

In sum, because the Examiner has not explained why an ordinary artisan viewing Trofast and Ashurst would have included a bulking agent as claimed in an aerosol propellant-containing composition, we are compelled to reverse the Examiner's rejection of claim 1, and its dependents, as being obvious over those references.

REVERSED

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